EASYMax L

Long Term Care Manual

EasyMax L Self-Monitoring Blood Glucose System

This Manual is intended for facilities where point-of-care testing is conducted by a healthcare professional. Please thoroughly read the EasyMax L Owner's Guide and all product instructions before making use of this Manual.

EASYMax L

EasyMax L Self-Monitoring Blood Glucose System

Manufactured by:
EPS Bio Technology Corp.
No.8, R&D Road III, Hsinchu Science Park
Hsinchu, Taiwan 30077

Customer Service: 1-866-994-3345 (Toll Free)
(Mon-Fri 9:00 AM - 9:00 PM)

Introduction

This manual has been created for Healthcare professionals for the purposes of performing point-of-care testing.

Caution: Please carefully read the User's Manual and all product instructions before using this Long Term Care Manual and administering blood glucose tests.

Summary of Contents:

- An outline of the EasyMax L Self-Monitoring Blood Glucose Test System.
- Quality Control Method, including how to troubleshoot potential issues that may arise while performing EasyMax blood glucose tests.
- Training information for healthcare professionals

Intended Use:

The **EasyMax L Self-Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Questions?
If you have questions or need assistance, please call Customer Service toll-free at 1-866-994-3345 (Eastern Time, Mon-Fri 9:00 am-9:00 pm). You can also visit www.oaktree-int.com for diabetes management tools and product demonstrations.

Important Information About the EasyMax L System:

- EasyMax L blood glucose meter is designed and approved for testing fresh capillary whole blood samples from your fingertip and forearm. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- EasyMax L blood glucose meter can only be used with EasyMax Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect reading. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- The system should be used at a temperature between 50°F-104°F (10°C - 40°C). Outside this range, the system may get incorrect results.
- You should not store the meter and test strips in a car, bathroom, or refrigerator.
- *Elevated levels of acetaminophen, uric acid, gentisica acid, levodopa, dopamine, ascorbic acid and methyldopa may affect results.*
- Remove batteries if the meter will not be used for one month or more.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle, and once opened the strips have a 90 day shelf life).
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level has no effect on readings.
- DO NOT reuse the test strips. The test strips are for single use only.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

- You should not test critically ill patients with home-use blood glucose meters.
- Patients undergoing oxygen therapy may have inaccurate results.
- If the patient has the following conditions, the result may fail:
  - Severe dehydration
  - Severe hypotension (low blood pressure)
  - Shock
  - A state of hypoglycemic-hyperosmolar state (with or without ketosis)
- Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EasyMax L Glucose Meter.

Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Interfering Substance	Test Concentration mg/dl	Bias at 50±5 mg/dl	% Bias at 250±5 mg/dl	% Bias at 500±5 mg/dl
Acetaminophen	8	10.2	6.5	3.8
Ascorbic Acid	2.5	11.8	-6.8	5.3
Dopamine	2	4.3	12.9	6.3
Gentisic Acid	6	7.8	2.8	-4.3
L-Dopa	2	3.8	-1.2	-1.8
Methyldopa	2	5.2	-2.3	4.1
Uric Acid	13	7.6	3.9	3.8

Alternate Site Testing (AST)
EasyMax L gives patients the option to test on their fingertip or forearm. Blood glucose test results obtained from the forearm may differ significantly from fingertip samples.

It is preferred that you Do NOT perform Alternate Site Testing (AST) if:
- Your patient has frequent low blood glucose.
- Your patient is unaware of hypoglycemia.
- The AST results do not match the way the patient feels.
- You are testing for hyperglycemia.
- The patient's routine glucose results are often fluctuating.
- If the patient is pregnant.

Quality Control

If you are using the EasyMax L and the result seems lower or higher than expected, it is recommended that you repeat the test with a new strip. If you get the same result, please conduct a control solution test to ensure your meter and test strips are working properly.

If you are evaluating the EasyMax L results and are comparing it to lab results, please note that the patient should be fasting and the fingertip test should occur within five minutes of having blood drawn. It is also important to know that the lab technology may be different than the EasyMax L technology; therefore results may not always be a complete match.

EasyMax L System

Specifications

Brand Name		**EasyMax L Blood Glucose Meter**
Range		20~600 mg/dL
Test Time		5 Seconds
Memory Sets		480 Test Results
Operating Condition	Temp.	50^0F~104^0F (10^0C~40^0C)
	Relative Humidity	R.H. < 90%
Blood Sample		0.6 µL
		Fresh Blood from Fingertip or Forearm
Hematocrit (Hct)		30~55%
Power		CR2032 Lithium Cell (3V (2 ct)
Battery Life		Over 2,000 Tests
Display Dimension		1.70” x 1.38” (43 x 35 mm)
Device Dimension H x W x D (mm)		3.39” x 1.85” x 0.54” (86 x 47 x 13.8 mm)
Weight		1.517 oz (43 Grams) w/o Batteries
Principles		Electrochemical Biosensor Technology

Caring for your Blood Glucose Meter in a LTC Setting

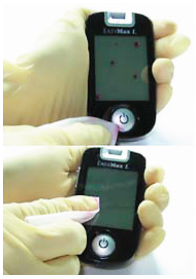
In order to prevent the growth of microorganism, make sure you cover all the steps below.

1. Make sure the meter is off.

2. Put on a pair of protective gloves before you start the cleaning procedure

3. Sanitize the glucose meter with any EPA approved disinfectant product that meets the 1:10 bleach solution.

4. Wipe the surface of the glucose meter including the test strip port and USB port after each use. Be careful to make sure no liquid goes into either port. Wipe the meter thoroughly; the treated surface must remain visibly wet for a full 2 minutes to attain complete disinfection.

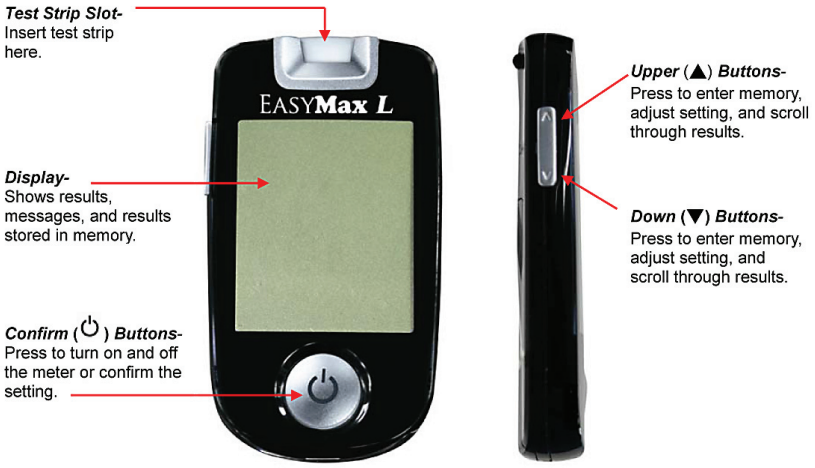


5. If you find any blood stains on the device, make sure you clean it with caution.

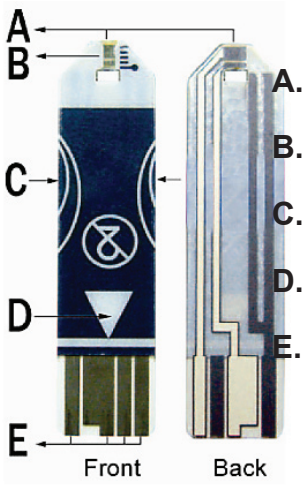
6. Air dry the meter to sanitize completely before next use.

The EasyMax L Blood Glucose Meter

	The Overview of the Display	Meaning
A	month and date	Shows the month and date
B	Memory	The meter will automatically record all test results
C	Error	The meter system is in fault
D	Test result	Shows the test result
E	Thermometer	The themometer icon appears when the temperature is too high or too low
F	Application of blood or control solution	Test your level of blood glucose
G	Time	Shows the time
H	PC	Connect to the PC
I	Sound volume	Beep function can be turned on/off
J	Insert test strips	Insert the test strip to start testing blood glucose
K	Glucose unit	The testing unit of blood glucose
L	Battery status	When the battery symbol appears prepare other batteries for installation


Test Strip Slot-
Insert test strip here.
Display-
Shows results, messages, and results stored in memory.
Confirm (⏻) Buttons-
Press to turn on and off the meter or confirm the setting.
EASYMax L
Upper (▲) Buttons-
Press to enter memory, adjust setting, and scroll through results.
Down (▼) Buttons-
Press to enter memory, adjust setting, and scroll through results.

EasyMax Test Strip



A. Blood Collection Area

B. Reaction Area

C. Hand Hold Area

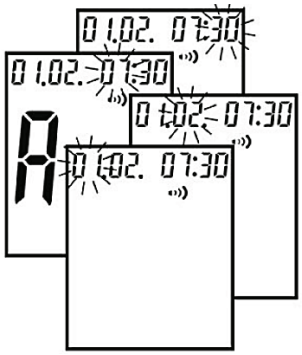
D. Strip Insert Direction

E. Electrode

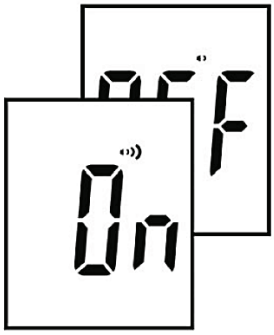
Setting the Time, Date and Sound Volume-First Time Use

Setting the current time and date in your meter is important if you use the meter memory.

1. Insert batteries, the meter turns on automatically.
2. The last 2-digits of the year flash at the top of the display. Press "▲" or "▼" to adjust the year and press ⏻ to confirm setting.



3. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting. (A=AM, P=PM)



4. Press "▲" or "▼" to turn on or turn off the volume and press ⏻ to confirm the setting.

Note: The unit of Blood Glucose Meter is set at mg/dL without any modification function.

You can also set the time, date and sound volume without replacing the batteries.

1. Keep pressing "▲" until you see the "SEL". After 2 seconds the meter enters the setting mode automatically.

2. Repeat step 2 to 4 above to set the year, date, time and sound volume. The flashing field is the one you are currently setting.

Memory, Storing Test Results

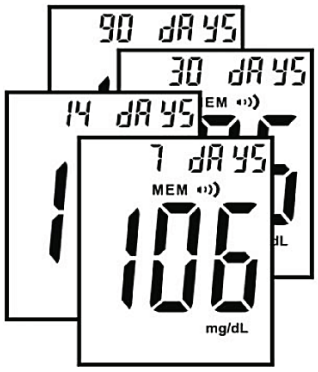
This meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Note:

1. The memory is not lost when you replace the battery. The time and date will remain correct.
2. Once 480 results are in memory, adding a new result causes the oldest one to be deleted.
3. Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging test results.

Viewing & Deleting Results

1. Press "▼" to view the test result.
2. Press "▼" to view the previous results in order from the latest to the earliest.



3. Or press "▲" to view averages of 7/14/30/90 days test result.

4. While viewing a result, if you would like to delete it, press for 3 seconds. When the display shows "dEL", the memory is successfully removed.
5. Then press "▲" or " " to keep reviewing the rest of the test results.

Running a Control Solution Test

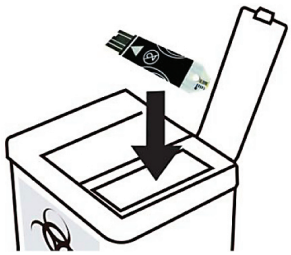
You need the meter, a test strip, and control solution

1. Put a test strip into the meter in the direction of the arrow. The meter will automatically turn on.
2. Press "▲" or "▼", the display shows "CtL" and the meter is ready to run a control solution test.

3. Place the meter on a flat surface, like a table.
4. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.
5. Squeeze the bottle until a tiny drop forms at the top of the bottle.

6. Touch the drop to the Blood collection area at the end of the test strip. **Do not put control solution on top of the test strip.** When you hear the meter beep, you have enough control solution on the test strip. The meter starts to count down from 5 seconds and will show the results.

7. A result appears on the display. Don't remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.



8. Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.

Expiration date.
This date applies to unopened bottles only. Once opened, the control solution has a shelf life of 90 days.

Understanding Control Solution Test Results

Important: Please follow your institution's control solution testing regulations and procedures.

The label on your test strip bottle shows the acceptable ranges for the Control Solution. The result you get should be inside this range. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range (See 1A) on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range, here are some things you can do to solve the problem:

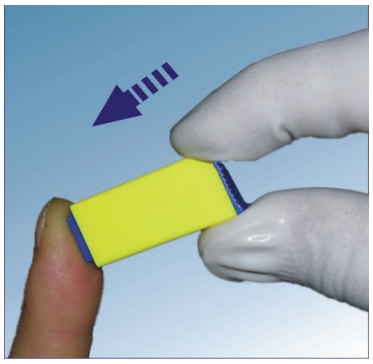
1A

Troubleshooting Checks	Action
Was the test strip exposed to open air for a long period of time?	Repeat the control test with properly stored strips.
Was the test strip bottle capped tightly?	This will humidify strips inside. Replace the test strips.
Is the control solution expired or contaminated?	Replace with new control solution to check the performance of the system.
Were test strips and control solutions stored in cool, dry places?	Repeat the control test with properly stored strips and/or control solutions.
Did you follow the testing steps properly?	Read Chapter 2 in the manual "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results. Call Customer Service Toll-Free: 1-866-994-3345 (Eastern Time, Mon-Fri 9:00 am - 9:00 pm)

Performing a Blood Glucose Test
Please adhere to your institution's medical device handling and site preparation procedures.

1. Wash your patient's hands with soap and warm water. Rinse and dry thoroughly. Your institution may require that you use an alcohol prep pad. Please ensure that the test site is completely dry before proceeding.

2. Put a test strip into the meter in the direction of the arrow. The meter will automatically turn on.



3. Please wait at least 5 seconds until the intended area is dry and clean before sampling the blood.
4. When the blood drop flashes on the display, obtain a drop of blood from fingertip, using a safety lancet. (See image above)

In a Long Term Care facility setting, we recommend that a **safety lancet** be used for each individual blood glucose test. For demonstration purposes, we are using SteriLance™'s Pressure Activated Safety Lancets.

1. Carefully pull off the protective cap.
2. Push the lancet firmly onto the chosen site to fire.
3. Gently apply intermittent pressure near the puncture site to obtain the required blood volume. EasyMax L system requires a small 0.6 microliter blood sample.

5. Touch the drop of blood to the tip of the transparent window of the test strip. Do not put blood on top of the strip. Be sure to get enough blood on the strip's reaction zone. Otherwise, an inaccurate reading may result.

6. The meter will beep when enough blood has entered the strip's reaction zone. The result will appear on the display after 5 seconds.

7. Discard the used safety lancet and test strip into an appropriate sharps or biohazard container.

Troubleshooting Screen Messages

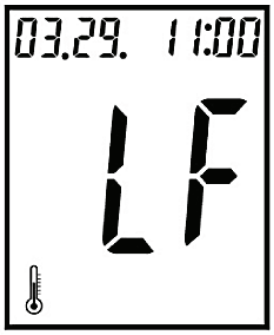
Please do not make treatment decisions based on an error message. If you have any concerns, please contact Customer Service Toll-Free: 1-866-994-3345 (Eastern Time, Mon-Fri 9:00 am - 9:00 pm).

Humidified/Used strips
Action: Replace with a new strip.

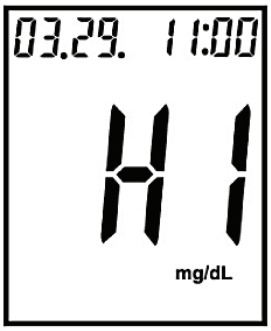
Low Power
Action: Replace with new batteries.

System Fault
Action: Replace the batteries first. If 001 ERROR appears again, please call Customer Service toll-free 1-866-994-3345.

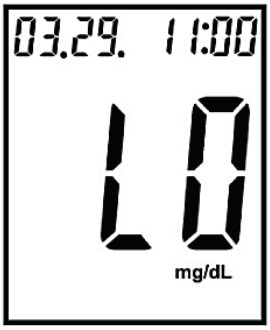
The "HF" and thermometer icon appears. Temperature is too high, outside the required range of 50^{0}F-104^{0}F (10^{0}C-40^{0}C). This alerts users that an incorrect result may occur if the test continues.
Action: Relocate the meter to a location with temperature between 50^{0}F-104^{0}F (10^{0}C-40^{0}C).



The "LF" and thermometer icon appears. Temperature is too high, outside the required range of 50^{0}F-104^{0}F (10^{0}C-40^{0}C). This alerts users that an incorrect result may occur if the test continues.
Action: Relocate the meter to a location with temperature between 50^{0}F-104^{0}F (10^{0}C-40^{0}C).



Test result is higher than 600 mg/dL.
Action: Test again. If the result is still the same, please call Customer Service toll-free 1-866-994-3345.



Test result is lower than 20 mg/dL.
Action: Test again. If the result is still the same, please call Customer Service toll-free 1-866-994-3345.

EASYMax L

EasyMax L Self-Monitoring Blood Glucose System

Training Information
for
Healthcare Professionals

EasyMax L System Trainer Checklist

You may use the following checklist to assess the trainee's ability to perform the following tasks.

1. Identifies the equipment used with the EasyMax L System.

_____ EasyMax L Blood Glucose Monitor
_____ EasyMax Blood Glucose Test Strips
_____ EasyMax Control Solutions: Low, High, Normal
_____ Safety Lancet

2. Blood Glucose Meter

_____ Locates the serial number
_____ Identifies the strip slot
_____ Locates the on/off button
_____ Locates the setting button

3. Blood Glucose Test Strip

_____ Locates the expiration date (opened & unopened)
_____ Checks the lot number
_____ Identifies the blood collection area
_____ Understands the correct strip insert direction
_____ Locates the electrode end of test strip
_____ Identifies the designated "hand hold" area

4. Demonstrates proper test strip use

_____ Only uses EasyMax blood glucose meters with EasyMax blood glucose test strips
_____ Runs a control solution test every time a new vial of test strips are opened
_____ Keeps test strips in their original vial
_____ Closes vial immediately after taking a test strip out, to eliminate the contamination of the other test strips
_____ Knows test strips are single use only. Do not re-use.
_____ Records the date the test strip bottle is opened. Checks the "Expiration Date" on the test strip bottle. The test strips are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
_____ Stores the test strips between 35.6^{O}F - 86^{O}F. Do not freeze.
_____ Follows proper disposal of used test strips according to your institution's policy.

5. Demonstration of blood glucose testing.

_____ Demonstrates proper safety lancet technique when collecting blood sample
_____ Understands the different sites that may be used with the meter
_____ Demonstrates appropriate disposal of safety lancet in accordance with institution's policy
_____ Demonstrates the correct way to insert the test strip into meter
_____ Understands symbols that appear on the meter screen and what, if any, corresponding action
_____ Demonstrates correct placement of blood on test strip
_____ Records results as specified per your institution
_____ Understands the protocool for inaccurate results (re-tests, control solution test, troubleshoot)
_____ Knows the actions to be taken when results are abnormally high or low

6. Quality Control

_____ Performs a control solution test, and can explain why it should be done
_____ Understands the dates listed on the control solution and how they apply to opened vs unopened vials
_____ Recognizes what it means when a control solution test result falls in the range listed on the vial, and when the test result falls out of the range on the vial

7. Troubleshooting Guidelines

_____ Understands the steps to follow when troubleshooting
_____ Knows the warranty of meter
_____ Knows how to handle defective meter, strips, etc. (next steps, manufacture customer service\service phone number)

8. Proper Care

_____ Understands how to maintain the meter
_____ Locates proper storage
_____ Demonstrates proper cleaning
_____ Demonstrates proper battery installation

9. Documentation

_____ Understands what information must be documented by law and what is required by your institution.

EasyMax L Quiz

This quiz is multiple choice, fill in the blank, and true/false.

1. The EasyMax L system does not require calibration.

   True False

2. EasyMax control solution, once opened and assuming the expiration on the vial has not expired first, has an expiration date of:
   A. 60 days
   B. 6 months
   C. 3 months
   D. 45 days

3. You should perform a control solution test when:
   A. You think the meter or test strips may be working incorrectly.
   B. You drop the meter.
   C. You have repeated a test and the test results are still lower or higher than expected.
   D. All of the Above

4. When performing a blood glucose test, where should you apply the blood?
   A. On top of the test strip
   B. On the side of the test strip
   C. The tip of the test strip
   D. The middle of the test strip

5. When conducting a quality control test, which of the following steps will be taken?
   A. Turn the meter off and on again.
   B. Push the setting button twice.
   C. Change the battery
   D. Perform a control solution test

6. If you are performing a blood glucose test, and you get this error, what should you do first?

   A. Re-test
   B. Replace the battery
   C. Turn the meter off and on again
   D. Replace with a new strip

7. The memory will store _____ results.
   A. 300
   B. 250
   C. 480
   D.1000

8. Name two substances that have the potential to interfere with an accurate blood glucose result.

_____

_____

9. Describe how test strips should be inserted into the meter.

_____

_____

10. If you get this message, the blood glucose result is lower than _____ mg/dL.

11. What type of battery does the EasyMax L require?
    A. 3 Volt Lithium
    B. Alkaline 1.5 Volt (AAA)
    C. Alkaline 1.5 Volt, (AAAA)
    D. None of the above

12. Describe the proper way to dispose of a safety lancet.

_____

_____

13. The appropriate way to clean the meter is:

_____

_____

Answers available upon request.

EasyMax L Blood Glucose Quality Control Results Log

Facility Name:_____ Monitor #_____

Month/Year:_____ Results Reviewed by:_____

Date	Time	Staff Performing	Test Strip Lot#	Low Control			Normal Control			High Control			Action Taken
				Lot	Range	Result	Lot	Range	Result	Lot	Range	Result	